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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,102	07/31/2001	Howard Fein	HOFE / 02	2446
26875	7590	12/04/2003	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			WITZ, JEAN C	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/919,102	FEIN, HOWARD	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-2 and 4-63 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

In view of the claims that had not been present in the Application at the time of the first Restriction Requirement, the Examiner has withdrawn the previous restriction requirement and substituted the following restriction requirement that takes into account Applicants' amendments and newly submitted claims. Applicant's election with traverse is acknowledged. The traversal is on the ground(s) that the election of species is improper. For purposes of information, the Examiner will address this traversal.

Applicant's reliance on the Weber decision cited in Applicant's response to the previous restriction requirement is misplaced. This case addressed the rejection of claims under 35 USC 121; the Examiner has not rejected any claims of record. Applicant's assertion that a requirement to elect a species is a "refusal to examine" is not well taken. Per MPEP 803.02, a Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims

drawn to species patentably distinct from the elected species held withdrawn from further consideration.

While Applicant appears to assert that the hydrolases recited in claim 9 are so related by their ability to transfer a donor group to water that they are not independent and distinct, this interpretation is inconsistent with conventional biological chemical use of these enzymes since the number of hydrolases listed in the Enzyme Nomenclature text published by the International Union of Biochemistry run from page 270 to page 393 and list multitudinous numbers of hydrolases with very specific substrates. Suffice to say that a peptidase will have no effect on a mucin substrate, while a mucinase will have little effect on a peptide. Therefore, the fact that their action of transferring donor groups does not sufficiently link them to render Applicant's list in his Markush Group at consisting of a single invention.

Finally, Applicant's disagreement that the treatment of skin conditions can be practiced with a materially different product is not persuasive. Applicant's argument of "nonspecific damage" is not germane because the claim does not include this in its preamble or method steps. In addition to alpha-hydroxy acids, other conventional treatments of at least one layer of skin include antibiotics to treatment of infections, 5-fluorouracil for treatment of carcinomas, benzoyl peroxide for treatment of acne and comedones, and hydrocortisone for treatment of atopic dermatitis. There are multitudinous numbers of non-enzymatic treatments for the skin conditions recited in the claims; therefore, these treatments provide evidence of independence and distinctness of the compositions versus the methods.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 4-10, 24-63, drawn to methods of treating a condition affecting at least one layer of the skin, classified in class 424, subclass 94.6.
- II. Claims 11-19, drawn to an enzyme-containing composition, classified in class 424, subclass 94.63.
- III. Claims 20-23, drawn to an enzyme-containing composition, classified in class 424, subclass 94.6.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the invention of Group II is limited to a specific class of hydrolases, the peptidases. The subcombination has separate utility such as enzymatically degrading molecularly different substrates such as cellulose or lipids.

Inventions of Groups I and Groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the enzymes in Groups II and III can be used for a myriad of different purposes such as isolation of hematopoietic stem cells from liposuctioned fat (collagenase and/or trypsin) and in clot reduction (plasminogen activator).

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

In Group I, the following species are claimed:

- 1) Species of the conditions listed in claims 42-63 as well the conditions listed in claim 33;
- 2) Species of enzymes listed in claim 9

If Applicant elects Group I, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the condition and a single disclosed species for the enzyme for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 2, 4, 8-10, 24-27, 29-32 are generic.

In Group III, the following species are claimed:

- 1) Species of enzymes listed in claim 23

If Applicant elects Group III, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the condition and a single disclosed species for the enzyme for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 20-23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

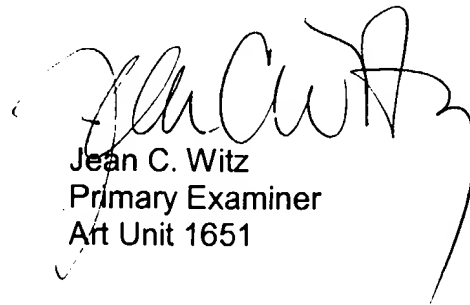
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jean C. Witz  
Primary Examiner  
Art Unit 1651